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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,772	10/06/2003	Barry M. Yomtov	17509-0075	5967

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EXAMINER	
ALTER, ALYSSA MARGO	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/679,772	**Applicant(s)** YOMTOV ET AL.	
	Examiner Alyssa M. Alter	**Art Unit** 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-24,26-30,33-35 and 54-63* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-4,7-24,26-30,33-35 and 54-63* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2008 has been entered.

Response to Arguments

Applicant's arguments, see page 4, filed November 8, 2006, have been fully considered but they are not persuasive.

The Applicant argues that Sheppard, Jr. et al. does not disclose flowing electrical current through the reservoir cap in an amount effect to electrothermally ablate, i.e. rupture, the reservoir cap."

However, Sheppard, JR. et al. does disclose on page 3, paragraph 27, "the reservoir cap includes an electrically- or thermally-responsive polymer whose integrity or porosity can be modulated (i.e. increased or decreased) upon application of electrical energy to the reservoir cap (e.g., for the electrically responsive polymer) or to a nearby resistor (e.g., for the thermally responsive polymer)". Therefore, electrical current does flow through the reservoir cap.

The Applicant further argues that the examiner "improperly ignored evidence of record". However, in accordance with the Office Action sent dated 10/25/2006, the examiner considered the Declaration.

Therefore, the claims are rejected under Sheppard, JR. et al., as necessitated by amendment, rejection below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-4, 7-14, 16-24, 29-30, 33-34 and 55-63 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheppard, JR. et al. (US Patent Publication 20020072784). Sheppard, JR. et al. discloses a microchip device that “can be ex vivo or in vitro, but more preferable for in vivo application”(page 5, paragraph 48) for the delivery of a drug.

Sheppard, JR. et al. does disclose on page 3, paragraph 27, “the reservoir cap includes an electrically- or thermally-responsive polymer whose integrity or porosity can be modulated (i.e. increased or decreased) upon application of electrical energy to the reservoir cap (e.g., for the electrically responsive polymer) or to a nearby resistor (e.g., for the thermally responsive polymer). Similarly, the reservoir cap can include or be formed of a polymer having a porosity that can be modulated by application of electromagnetic energy, acoustic energy, or a particular chemical species (e.g., for chemical actuation) provided by the microchip device or other source”.

Therefore, since the caps are constructed from an electrically responsive polymer, that “upon the application of electrical energy to the reservoir cap” the cap disintegrates, it follows that they would release their contents by electothermal ablation. The electrothermal ablation of the caps is commensurate to the definition set forth by the Applicant in the specification (see Amendment to the Specification dated 11/8/06).

As to claim 1 and 55, Sheppard, JR. et al. discloses the claimed invention but is silent as to how the energy is conducted to the reservoir cap. However, in order to provide the reservoir cap with electrical energy, there would necessarily be conducting leads.

In the alternative, although the examiner considers Sheppard, JR. et al. to disclose conductive leads, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system as taught by Sheppard, JR et al. with conductive leads to provide the predictable results of ensuring that the electrical energy is properly conducted to the reservoir caps. Furthermore, it is well known in the art to employ conductive leads to transmit electrical energy.

As to claims 7-8, 11-13, 20 and 23, it has been held that the recitation that an element is “adapted to” perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

The microchip device includes one or more bisensors. “As used herein, the term "biosensor" includes, but is not limited to, sensing devices that transduce the chemical potential of an analyte of interest into an electrical signal, as well as electrodes that measure electrical signals directly or indirectly (e.g., by converting a mechanical or thermal energy into an electrical signal). For example, the biosensor may measure intrinsic electrical signals (EKG, EEG, or other neural signals), pressure, temperature, pH, or loads on tissue structures at various in vivo locations. The electrical signal from the biosensor can then be measured, for example by a microprocessor/controller, which then can transmit the information to a remote controller, another local controller, or both” (page 5, paragraph 51). “Additional support circuitry may be used to interface to biosensors or other types of devices such as pacemakers or defibrillators" (page 4, paragraph 44). Therefore the electrodes include cardiac pacing electrodes and cardioversion electrodes.

Since the microchip is used in conjunction with a pacemaker or defibrillator, the device is capable of regulating the drug. "The delivery of the drug or other molecule could be controlled by feedback from a biosensor located on or near the microchip, and interfaced to the controller" (page 6, paragraph 57). Furthermore, the "active microchip devices may be controlled by local microprocessors or remote control. Biosensor information may provide input to the controller to determine the time and type of activation automatically, with human intervention, or a combination thereof. The microchip devices have numerous in vivo, in vitro, and commercial diagnostic applications. The microchips are capable of delivering precisely metered quantities of molecules and thus are useful for in vitro applications, such as analytical chemistry and medical diagnostics, as well as biological applications such as the delivery of factors to cell cultures" (page 5, paragraph 53).

"The microchip reservoir contents can be essentially any chemical or miniature device. In a preferred embodiment, the chemical is a therapeutic, prophylactic, or diagnostic agent. (The term "drug" is used herein to refer any of these agents.) Preferred drug delivery applications include potent compounds, including both small and large (i.e. macro) molecules, such as hormones, steroids, chemotherapy medications, vaccines, gene delivery vectors, and some strong analgesic agents" (page 3, paragraph 28).

"The microchip systems are especially useful for drug therapies in which it is desired to control the exact amount, rate, and/or time of delivery of the drug" (page 5, paragraph 49). Since the microchip system controls the time and the rate, inherently the system is capable of having a predetermined delay.

"Each microchip device includes a substrate having a plurality of reservoirs containing reservoir contents for release or exposure. In a preferred embodiment, each reservoir has a reservoir cap positioned on the reservoir over the reservoir contents, wherein release or exposure of the reservoir contents is controlled by diffusion through or is integration of the reservoir cap. The reservoir cap can be an anode, such that upon application of an electric potential between a cathode and the anode the reservoir cap is oxidized to facilitate its disintegration, thereby exposing the reservoir contents to a surrounding fluid" (page 2, paragraph 26).

As to claims 19 and 22-23, since there is a computer monitoring system and ECG electrodes, the computer monitoring system is inherently an ECG monitoring system.

As to claim 55, Sheppard, JR. et al. discloses on page 4, paragraph 46 the employment of "metal film reservoir caps".

As to claim 62 and 63, the material forming the reservoir cap would naturally have a lower melting temperature than the material forming the conductive leads in order to effectively apply energy to remove the cap without melting the lead itself.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

2. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being obvious over Sheppard, JR. et al. (US Patent Publication 20020072784). Sheppard, JR. et al. discloses the claimed invention except for the external electrodes or sensors located on the ourter surface or at a distance from a hermetically sealed encasement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the controlled drug delivery device as taught by Sheppard, JR. et al. with the electrodes or sensors located on the outer surface of the housing or at a distance from the housing, since such a modification would provide the predictable results of increasing the stimulation or sensing area and providing a larger area of treatment. Furthermore, it is well known in the art to employ electrodes or sensors on the exterior of a hermetically sealed medical device, as well as position electrodes or sensors at a distance from a medical device.

3. Claims 15 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Sheppard, JR. et al. (US Patent Publication 20020072784) in view of Fischell et al. (US 6,112,116). Sheppard, JR. et al. discloses the claimed invention except for the delivery of the anti-arrhythmic drug. Fischell et al. discloses the delivery of anti-arrhythmia

medication from an implantable system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the released drugs as taught by Sheppard, JR. et al. with the anti-arrhythmia drugs as taught by Fischell et al., since such a modification would help terminate arrhythmias and modify treatment to meet specific patients needs and therapeutic requirements.

4. Claim 35 is rejected under 35 U.S.C. 103(a) as being obvious over Sheppard, JR. et al. (US Patent Publication 20020072784) in view of Theeuwes et al. (US 6,726,920). Sheppard, JR. et al. discloses the claimed invention except for the natriuretic peptide. Theeuwes et al. teaches that it is known to use brain natruretic peptide as set forth in column 6, lines 8-19, as a cardiac drug to treat a cardiac condition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the hormone delivery as taught by Sheppard, JR. et al. with the natriuretic peptide, which is also a hormone, as taught by Theeuwes et al., in order to modify treatment to meet specific patients therapeutic requirements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
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